REMARKS

Reconsideration and allowance in view of the foregoing amendment and the following remarks are respectfully requested.

The applicant and the undersigned wish to thank Examiner Shay for the courtesies extended during the interview of December 4, 2003. The amendment discussed during the interview and the arguments made are repeated herein for the record.

The title and specification have been amended above as suggested by the Examiner.

The Examiner noted that claims 23-35 are withdrawn from further consideration. To advance prosecution, claims 23-35 have been canceled above. Applicant reserves the right to file one or more divisional applications directed to the subject matter of the non-elected and now canceled claims.

Claims 1-19, 21, 22 and 36 are now pending.

Claims 13-20 were rejected under 35 USC 112, second paragraph, as being indefinite. These claims have been reviewed and revised above so as to more affirmatively include method limitations as suggested by the Examiner. The claims have also been amended to correct discovered typographical errors and to delete "step of" so that the respective elements are not mistakenly considered to be in "means plus function" format. It is believed that all claims are now in full compliance with 35 USC 112, and it is therefore respectfully requested that the rejection be withdrawn.

Original claims 1, 2, 4, 7, 12-15, 21 and 22 were rejected under 35 USC 102(b) as clearly anticipated by Mizuno. Applicant respectfully traverses this rejection.

The inventors have developed a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. More specifically, the inventors have developed a technique for accessing the peritoneal cavity via a wall of the digestive tract. To provide

such access, an elongated flexible conduit is positioned to extend from the exterior of the patient through a natural orifice, into and along a portion of the digestive tract, to a target wall segment. An incision is then formed in the target wall segment and the distal end of the flexible conduit is advanced to extend through the incised wall. Once the distal end of the flexible conduit is anchored with respect to the wall, an endoscope can be advanced through the conduit so that the surgeon can view tissues and/or organs within the accessed cavity.

Anticipation under Section 102 of the Patent Act requires that a prior art reference disclose every claim element of the claimed invention. See, e.g., Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1574 (Fed. Cir. 1986). While other references may be used to interpret an allegedly anticipating reference, anticipation must be found in a single reference. See, e.g., Studiengesellschaft Kohle, G.m.b.H. v. Dart Indus., Inc., 726 F.2d 724, 726-27 (Fed. Cir. 1984). The absence of any element of the claim from the cited reference negates anticipation. See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984). Anticipation is not shown even if the differences between the claims and the prior art reference are insubstantial and the missing elements could be supplied by the knowledge of one skilled in the art. See, e.g., Structural Rubber Prods., 749 F.2d at 716-17.

It is respectfully submitted that Mizuno does not teach or in any way suggest the claimed positioning of a flexible conduit to extend from an exterior of the mammal/patient through a natural orifice, forming an incision in a target wall segment, advancing the distal end of the flexible conduit through the incised wall, and anchoring the distal end of the flexible conduit to the wall.

The Examiner has referred to Figures 37A and B of Mizuno as allegedly anticipating the invention claimed in claim 1. However, as noted above, the claimed positioning, forming, advancing and anchoring limitations of claim 1 are not anticipated by the embodiment illustrated in Figures 37A and B of Mizuno. In this regard, Mizuno teaches advancing an endoscope 301 through the patient's mouth and to a diseased

wall portion of the digestive tract (see Figure 38). Endoscope 301 does not anticipate an elongated flexible conduit through which an endoscope is advanced. Mizuno further discloses that a manipulator 302 is advanced through the abdominal wall and has a hall detector 321 for detecting a magnet 316 on the endoscope 301, to locate the manipulator in facing relation to the endoscope 301. Before any tissue incision or treatment is performed, the manipulator 302 and the endoscope 301 capture a target tissue region between them, as shown in Figure 37B, and then the diseased tissue is cut or otherwise treated by the endoscope.

As will be understood, in the procedure disclosed by Mizuno, no flexible conduit is advanced to a target wall segment nor is a flexible conduit advanced through an incised wall and anchored to the wall. According to Mizuno's teaching, the endoscope itself is ultimately anchored to the wall with the aid of manipulator 302 and all this is performed before any incision of the target wall. Therefore, while Mizuno bears superficial similarities to the invention, Mizuno does not in fact teach or suggest the method of the invention as specifically recited in claim 1.

It is further respectfully submitted that it would be unobvious to modify Mizuno so as to produce the invention. In this regard, Mizuno clearly teaches isolating the diseased wall segment between the manipulator and the endoscope before any treatment or incision is carried out on the wall segment. Thus, Mizuno clearly does not teach or suggest forming an incision and advancing a flexible conduit through the (incised) wall, and it would be unobvious to the skilled artisan to modify Mizuno to perform any incision before his anchoring/isolating steps. It is therefore respectfully submitted that a rejection of claim 1 and the claims dependent therefrom, based on Mizuno, cannot be sustained.

Claims 1 and 3 were rejected under 35 USC 103(a) as unpatentable over Mizuno in combination with Inoue. Applicant respectfully traverses this rejection.

In order to prove obviousness, a challenger must present prior art references which disclose the claimed subject matter of the patent/application in question. If

separate prior art references each disclose separate elements of a claim, the challenger must also show some teaching, suggestion, or incentive in the prior art that would have led one of ordinary skill in the art to make the claimed combination. See, e.g., Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 n.24, 304-05 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). In determining obviousness, there must be some reason other than hindsight for selectively combining the prior art references to render the claimed invention obvious. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985).

Claims 1 and 3 are submitted to be patentable over Mizuno for the reasons advanced above, The Examiner's further reliance on Inoue does not overcome the deficiencies of Mizuno noted above. It is further respectfully submitted that it would be unobvious to the skilled artisan to dilate any incision made by Mizuno. In this regard, Mizuno clearly teaches isolating a diseased tissue area before any incision or other treatment thereof is carried out. It would be unobvious in view of Mizuno and/or Inoue, without the benefit of applicant's invention, to incise the diseased tissue and/or dilate it before the isolation/anchoring he teaches. Indeed, disrupting the diseased tissue would have potentially disastrous results for the patient. It is therefore respectfully submitted that it would be unobvious to add dilating to Mizuno's procedure as disclosed in the embodiment of Figures 37A and B. In view of the foregoing, reconsideration and withdrawal of this rejection are requested.

Claims 1, 4 and 5 were rejected under 35 USC 103(a) as unpatentable over Mizuno et al in combination with Vander Salm et al. Applicant respectfully traverses this rejection.

While applicant acknowledges that insufflation of the peritoneal cavity, *per se*, is known, it would be unobvious to perform insufflation in the Mizuno et al procedure from the stomach side. In this regard, Mizuno does not teach or suggest a flexible conduit as claimed in the first instance and therefore there would be no need in Mizuno to define an airtight seal about the Mizuno endoscope much less insufflate through any such flexible conduit. Moreover, since Mizuno teaches a procedure performed on diseased

tissue of the digestive tract wall itself, and the endoscope is maintained entirely within the digestive tract throughout the procedure, with the tissue clamped between the manipulator and the endoscope, there would be no apparent need to insufflate in Mizuno, much less from the digestive tract side of the patient. Indeed, if any insufflation were performed in Mizuno, it would be performed through a separate access port provided through the patient's abdominal wall and would not be conducted from the endoscope side of the digestive tract wall. Therefore, it would be unobvious to modify Mizuno so as to satisfy the limitations of applicant's claims 4 and 5. In view of the foregoing, reconsideration and withdrawal of this rejection are requested.

Claims 1 and 6 were rejected under 35 USC 103(a) as unpatentable over Mizuno et al in combination with Shermeta. Applicant respectfully traverses this rejection.

As noted above, Mizuno does not teach a flexible conduit as claimed by applicant. Moreover, in accordance with Mizuno's teachings, a segment of digestive tract wall is captured and isolated between the manipulator and the endoscope. The use of a dual balloon fixation method would be inconsistent with the Mizuno procedure as the Shermeta balloon anchor is used for a tube that passes through a wall and in fact precludes access to the region around the incision. In contrast, Mizuno does not propose to advance any instrument or conduit through a wall but rather isolates a wall segment by clamping it between a manipulator and an endoscope. The skilled artisan would see no use or advantage to a balloon anchor in a procedure of the type taught by Mizuno. Therefore, the proposed modification of the Mizuno procedure is not one that would be made by the skilled artisan in the absence of applicant's disclosure.

Claims 1 and 7-19 were rejected under 35 USC 103(a) as unpatentable over Mizuno et al in combination with Wilson-Cook Brochure. Applicant respectfully traverses this rejection.

These claims are submitted to be patentable over Mizuno for the reasons advanced above. The Examiner's further reliance on Wilson-Cook Brochure does not overcome the deficiencies of Mizuno noted above. Even if the skilled artisan chose to

use a retractable needle knife in the Mizuno et al procedure, the needle-knife would be used to remove the diseased tissue segment 323 and would not obviously be used to form an incision in the target wall segment for the passage and subsequent anchoring of a flexible conduit as is claimed in applicant's claim 1. Therefore, even if a needle-knife were used in the Mizuno procedure, the method specifically claimed by applicant for accessing an interior of a cavity of the mammal would still not be anticipated nor obvious. In view of the foregoing, reconsideration and withdrawal of the rejection of claims 1 and 7-19 is requested.

Claim 20 was rejected as unpatentable over Mizuno in combination with Wilson-Cook and further in view of Bard Brochure. Claim 20 has been incorporated above into claim 19 from which it depended. Applicant respectfully traverses this rejection.

The Bard Brochure teaches a balloon dilator for a billiary procedure. The Examiner argues that it would be obvious to include a dilation balloon on the needle knife of Wilson-Cook Brochure as incorporated in Mizuno. Applicant respectfully disagrees.

In accordance with the teachings of Mizuno, a diseased wall segment 323 is isolated by being clamped between an endoscope and a manipulator and then the diseased tissue is removed. As such, the diseased tissue would be cut away and there would be no use or advantage whatsoever to a dilating balloon. On the contrary, once the diseased tissue 323 is removed, the surgeon would wish to close the incision, not dilate it. Thus, Mizuno teaches no use whatsoever for a dilating balloon and the Bard Brochure does not teach or suggest a use for a dilating balloon in the procedure of the type taught by Mizuno's Figures 37A and B. Only applicant teaches the advantageous use of a dilating balloon following a decision by a needle knife to allow insertion through the incised wall of a flexible conduit, so that an endoscope can thereafter be advanced into the thus accessed cavity. In view of the foregoing, reconsideration and withdrawal of the rejection of original claim 20, now incorporated into claim 19, is respectfully requested.

As discussed during the interview, dependent claim 36 has been added above which more specifically provides that in a presently preferred embodiment, the method of claim 1 is performed in the absence of an incision through the abdominal wall. It is to be appreciated, however, that the invention is not necessarily limited to the recited absence of an abdominal incision. In this regard, the method of the invention has the unique advantage that a surgical procedure can be performed in the absence of an incision into the abdominal wall, but even if the surgeon chooses to form one or more incisions in the abdominal wall, the procedure of the invention allows selective access to the peritoneal cavity via a flexible conduit inserted through the digestive tract, which is not in any way taught or suggested by Mizuno.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited.

Respectfully submitted,

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